Skeletal Kinetics

FEB - 7 2012

A COLSON ASSOCIATE

510(k) Summary

General Information as required by 21 CFR 807.92 (a) (1)

Submitters Name/address:	Skeletal Kinetics® LLC 10201 Bubb Road Cupertino, CA 95014, USA
Date:	February 2, 2012
Contact Person:	Christine Kuo, Director, Regulatory Affairs and Quality Assurance Phone: (408) 350-5842 Fax: (408) 366-1077

Device Name as required by 21 CFR 807.92 (a) (2)

Trade Name:	Callos ProModel Bone Void Filler
Regulation Number:	21 CFR 888.3045
Regulation Name:	Resorbable calcium salt bone void filler device
Regulatory Class:	II
Product Code:	MQV

Predicate Devices as required by 21 CFR 807.92 (a) (3)

The subject device is substantially equivalent to the following legally marketed devices (predicates):MIIG® SR Bone Void Filler (K060011), PRO-DENSE™ Bone Graft Substitute (K070437) and Callos® Bone Void Filler (K051123).

Device Description as required by 21 CFR 807.92 (a) (4)

Callos ProModel Bone Void Filler is a moldable and biocompatible calcium phosphate/calcium sulphate composite bone void filler. The single-use Callos ProModel kit contains the necessary components for mixing of the bone void filler. The Callos ProModel sterile kit contains: Calcium Phosphate/Calcium Sulfate Powder, Dilute Sodium Silicate Liquid, a Mixing System (Mixer and Syringe) and a Cannula.

Intended Use as required by 21 CFR 807.92 (a) (5)

Callos ProModel is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, posterolateral spine, pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Callos ProModel is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The product provides a bone void filler that resorbs and is replaced with bone during the healing process

Summary of Technological Characteristics as required by 21 CFR 807.92 (a) (6)

Callos ProModel consists of calcium phosphate/calcium sulfate powder and sodium silicate solution; when mixed together it forms a paste that can be applied directly to the injured bone.

The intended use, operating principles, design features, and materials of Callos ProModel is substantially equivalent to predicate devices.

Summary of Non-clinical Tests as required by 21 CFR 807.92 (b) (1)

The results of biocompatibility testing demonstrated that Callos ProModel met the standards set forth in ISO 10993-1, Biological Evaluation of Medical Devices, and the radiation sterilization validation is in compliance to ANSI/AAMI/ISO 11137-2:2006.

Bench testing demonstrated that Callos ProModel is substantially equivalent to the marketed predicate devices. The results indicated that the device met performance criteria outlined for its intended use.

The animal study provided data that Callos ProModel elicited similar biologic response in a large animal critical size defect model as compared to predicate devices for its intended use.

Summary of Clinical Tests as required by 21 CFR 807.92 (b) (2)

Callos ProModel does not meet the criteria to require clinical testing.

Conclusion as required by 21 CFR 807.92 (3)

In vitro and in vivo performance demonstrate that Callos ProModel is substantially equivalent to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Skeletal Kinectics® LLC
% Ms. Christine Kuo
Director, Regulatory Affairs and Quality Assurance
10201 Bubb Road
Cupertino, California 95014

FEB - 7 2012

Re: K112383
Trade/Device Name: Callos® ProModel Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: January 17, 2012
Received: January 18, 2012

Dear Ms. Kuo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: **Indications for Use**

510(K) Number (if Known): K112383

Device Name: Callos® ProModel Bone Void Filler

Indications for Use:

Callos® ProModel Bone Void Filler is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, posterolateral spine, pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Callos ProModel is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Prescription Use (Per 21 CFR 801 Subpart D)	X	AND/OR	Over-the-Counter Use (21CFR 801 Subpart C	____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112383